IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. AJANTA PHARMA LTD., Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendant Ajanta Pharma Ltd. ("Ajanta"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Ajanta's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of its generic pharmaceutical products before the expiration of the patents in suit.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '362, '840, '109, '637 and '419 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Ajanta is a corporation organized under the laws of India and its principal place of business is located at 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West), Mumbai, Maharashtra 400067 India.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Ajanta. Upon information and belief, Ajanta is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Ajanta directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Ajanta purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Ajanta's generic products.

8. Upon information and belief, Ajanta admits that "Ajanta Pharma set its eye on entering the world's largest and most stringent pharmaceutical market--USA . . . In our quest for expansion in the regulated markets, we expect US market to be our key growth driver in the coming years . . . Our products are already on the shelf in US . . . Currently we have 27 final approved products by US Food and Drug Administration (FDA), which are either commercialized or in process of being commercialized. Additional 2 ANDAs is tentatively approved, and other 21

ANDAs are under review with the US FDA (as on 31st March 2019). We are further planning to file about 10-12 ANDA's every year." http://www.ajantapharma.com/generics.html (accessed Oct. 11, 2019).

9. Ajanta's ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Ajanta's intent to market and sell Ajanta's generic products in this judicial district.

10. Ajanta has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Ajanta intends to direct sales of its generic drugs in this judicial district, among other places, once Ajanta receives the requested FDA approval to market its generic products. Upon information and belief, Ajanta will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

11. Upon information and belief, Ajanta has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213718.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Ajanta is incorporated in India and may be sued in any judicial district.

FACTUAL BACKGROUND

The NDA

13. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

14. The FDA approved NDA No. 205422 on July 10, 2015.

15. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patents In Suit

16. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as Exhibit A.

17. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

18. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

19. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986 days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

20. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

21. The PTO issued the ’840 patent on January 8, 2013, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’840 patent is attached as Exhibit D.

22. Otsuka owns the ’840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

23. The ’840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

24. The ’840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

25. The PTO issued the ’109 patent on December 31, 2013, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’109 patent is attached as Exhibit E.

26. Otsuka owns the ’109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

27. The ’109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

28. The ’109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

29. The PTO issued the ’637 patent on December 12, 2017, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’637 patent is attached as Exhibit F.

30. Otsuka owns the ’637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

31. The ’637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

32. The ’637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

33. The PTO issued the ’419 patent on June 4, 2019, entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” A true and correct copy of the ’419 patent is attached as Exhibit G.

34. Otsuka owns the ’419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

35. The ’419 patent expires on October 12, 2032.

36. The ’419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

37. Upon information and belief, Ajanta filed ANDA No. 213718 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg (“Ajanta’s generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets.

38. Upon information and belief, ANDA No. 213718 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that no valid claim of the patents in suit will be infringed by the importation, manufacture, use, or sale of Ajanta’s generic products.

39. Otsuka received a letter sent by Ajanta, dated August 30, 2019, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 213718 (“Ajanta’s Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B), § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Ajanta’s Notice Letter notified Otsuka that Ajanta had filed ANDA No. 213718,

seeking approval to engage in the commercial manufacture, use or sale of Ajanta's generic products before the expiration of the patents in suit.

40. Plaintiffs commenced this action within 45 days of receiving Ajanta's August 30, 2019, Notice Letter.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

41. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

42. Upon information and belief, Ajanta filed ANDA No. 213718 seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the '362 patent.

43. Upon information and belief, Ajanta filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

44. Upon information and belief, in its ANDA No. 213718, Ajanta has represented to the FDA that Ajanta's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

45. Ajanta has actual knowledge of Otsuka's '362 patent, as evidenced by Ajanta's August 30, 2019, Notice Letter.

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more claims of the '362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213718, seeking approval to commercially manufacture, use, import, offer to sell or sell Ajanta's generic products before the expiration date of the '362 patent.

47. Upon information and belief, if ANDA No. 213718 is approved, Ajanta intends to and will offer to sell, sell and/or import in the United States Ajanta's generic products.

48. Upon information and belief, if ANDA No. 213718 is approved, Ajanta will infringe one or more claims of the '362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Ajanta's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213718 shall be no earlier than the expiration of the '362 patent and any additional periods of exclusivity.

49. Upon information and belief, Ajanta's actions relating to Ajanta's ANDA No. 213718 complained of herein were done by and for the benefit of Ajanta.

50. Plaintiffs will be irreparably harmed by Ajanta's infringing activities unless this Court enjoins those activities.

51. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '840 PATENT)

52. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

53. Upon information and belief, Ajanta filed ANDA No. 213718 seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the '840 patent.

54. Upon information and belief, Ajanta filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

55. Upon information and belief, in its ANDA No. 213718, Ajanta has represented to the FDA that Ajanta's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

56. Ajanta has actual knowledge of Otsuka's '840 patent, as evidenced by Ajanta's August 30, 2019, Notice Letter.

57. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more claims of the '840 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213718, seeking approval to commercially manufacture, use, import, offer to sell or sell Ajanta's generic products before the expiration date of the '840 patent.

58. Upon information and belief, if ANDA No. 213718 is approved, Ajanta will infringe one or more claims of the '840 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Ajanta's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213718 shall be no earlier than the expiration of the '840 patent and any additional periods of exclusivity.

59. Upon information and belief, Ajanta knows, should know and intends that physicians will prescribe and patients will take Ajanta's generic products for which approval is sought in ANDA No. 213718, and therefore will infringe at least one claim of the '840 patent.

60. Upon information and belief, Ajanta has knowledge of the '840 patent and, by its proposed package insert for Ajanta's generic products, knows or should know that it will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

61. Upon information and belief, Ajanta is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Ajanta's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

62. Upon information and belief, if ANDA No. 213718 is approved, Ajanta intends to and will offer to sell, sell and/or import in the United States Ajanta's generic products.

63. Upon information and belief, Ajanta's actions relating to Ajanta's ANDA No. 213718 complained of herein were done by and for the benefit of Ajanta.

64. Plaintiffs will be irreparably harmed by Ajanta's infringing activities unless this Court enjoins those activities.

65. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '109 PATENT)

66. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

67. Upon information and belief, Ajanta filed ANDA No. 213718 seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the '109 patent.

68. Upon information and belief, Ajanta filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '109 patent are invalid, unenforceable and/or not infringed.

69. Upon information and belief, in its ANDA No. 213718, Ajanta has represented to the FDA that Ajanta's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

70. Ajanta has actual knowledge of Otsuka's '109 patent, as evidenced by Ajanta's August 30, 2019, Notice Letter.

71. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more claims of the '109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213718, seeking approval to commercially manufacture, use, import, offer to sell or sell Ajanta's generic products before the expiration date of the '109 patent.

72. Upon information and belief, if ANDA No. 213718 is approved, Ajanta will infringe one or more claims of the '109 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Ajanta's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213718 shall be no earlier than the expiration of the '109 patent and any additional periods of exclusivity.

73. Upon information and belief, Ajanta knows, should know and intends that physicians will prescribe and patients will take Ajanta's generic products for which approval is sought in ANDA No. 213718, and therefore will infringe at least one claim of the '109 patent.

74. Upon information and belief, Ajanta has knowledge of the '109 patent and, by its proposed package insert for Ajanta's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

75. Upon information and belief, Ajanta is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Ajanta's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.

76. Upon information and belief, if ANDA No. 213718 is approved, Ajanta intends to and will offer to sell, sell and/or import in the United States Ajanta's generic products.

77. Upon information and belief, Ajanta's actions relating to Ajanta's ANDA No. 213718 complained of herein were done by and for the benefit of Ajanta.

78. Plaintiffs will be irreparably harmed by Ajanta's infringing activities unless this Court enjoins those activities.

79. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '637 PATENT)

80. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

81. Upon information and belief, Ajanta filed ANDA No. 213718 seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the '637 patent.

82. Upon information and belief, Ajanta filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

83. Upon information and belief, in its ANDA No. 213718, Ajanta has represented to the FDA that Ajanta's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

84. Ajanta has actual knowledge of Otsuka's '637 patent, as evidenced by Ajanta's August, 30, 2019, Notice Letter.

85. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213718, seeking approval to commercially manufacture, use, import, offer to sell or sell Ajanta's generic products before the expiration date of the '637 patent.

86. Upon information and belief, if ANDA No. 213718 is approved, Ajanta will infringe one or more claims of the '637 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Ajanta's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213718 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

87. Upon information and belief, Ajanta knows, should know and intends that physicians will prescribe and patients will take Ajanta's generic products for which approval is sought in ANDA No. 213718, and therefore will infringe at least one claim of the '637 patent.

88. Upon information and belief, Ajanta has knowledge of the '637 patent and, by its proposed package insert for Ajanta's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

89. Upon information and belief, Ajanta is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Ajanta's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.

90. Upon information and belief, if ANDA No. 213718 is approved, Ajanta intends to and will offer to sell, sell and/or import in the United States Ajanta's generic products.

91. Upon information and belief, Ajanta's actions relating to Ajanta's ANDA No. 213718 complained of herein were done by and for the benefit of Ajanta.

92. Plaintiffs will be irreparably harmed by Ajanta's infringing activities unless this Court enjoins those activities.

93. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '419 PATENT)

94. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

95. Upon information and belief, Ajanta filed ANDA No. 213718 seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the '419 patent.

96. Upon information and belief, Ajanta filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '419 patent are invalid, unenforceable and/or not infringed.

97. Upon information and belief, in its ANDA No. 213718, Ajanta has represented to the FDA that Ajanta's generic products are pharmaceutically and therapeutically equivalent to

Otsuka's REXULTI® Tablets.

98. Ajanta has actual knowledge of Otsuka's '419 patent, as evidenced by Ajanta's August 30, 2019, Notice Letter.

99. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more claims of the '419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213718, seeking approval to commercially manufacture, use, import, offer to sell or sell Ajanta's generic products before the expiration date of the '419 patent.

100. Upon information and belief, if ANDA No. 213718 is approved, Ajanta will infringe one or more claims of the '419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Ajanta's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213718 shall be no earlier than the expiration of the '419 patent and any additional periods of exclusivity.

101. Upon information and belief, Ajanta's actions relating to Ajanta's ANDA No. 213718 complained of herein were done by and for the benefit of Ajanta.

102. Plaintiffs will be irreparably harmed by Ajanta's infringing activities unless this Court enjoins those activities.

103. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Ajanta has infringed at least one claim of each of the patents in suit through Ajanta's submission of ANDA No. 213718

to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Ajanta's generic products in the United States before the expiration of the patents in suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Ajanta's making, using, offering to sell, selling or importing of Ajanta's generic products before the expiration of the patents in suit will infringe, actively induce infringement and/or contribute to the infringement of the patents in suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Ajanta's generic products shall be no earlier than the expiration date of the patents in suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Ajanta and all persons acting in concert with Ajanta from commercially manufacturing, using, offering for sale or selling Ajanta's generic products within the United States, or importing Ajanta's generic products into the United States, until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Ajanta and all persons acting in concert with Ajanta from seeking, obtaining or maintaining approval of the ANDA until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

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